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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JOEL E. BERNSTEIN

Appeal 2011-003575
Application 10/772,809
Technology Center 1600

Before DONALD E. ADAMS, FRANCISCO C. PRATS, and
JEFFREY N. FREDMAN, Administrative Patent Judges.

FREDMAN, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a drug composition which the Examiner has rejected under grounds of anticipation and obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Statement of the Case

Background

"The principal object of the present invention is to provide an oral remedy to patients suffering from chronic painful neuropathic or fibromuscular disorders in forms such as oral suspensions, tablets or capsules containing a low dose of a tricyclic antidepressant compound combined with a non-narcotic analgesic" (Spec. 2 ¶ 0006).

The Claims

Claims 9, 11, 12, 14, 15, and 17 are on appeal. Claim 9 is representative and reads as follows:

> 9. A composition for treatment of chronic pain consisting essentially of a combination of a low dose of a tricyclic antidepressant compound, said dose in the range 2.5-25 mg, and a standard dose of a non-narcotic analgesic in a single pharmaceutically acceptable vehicle for oral administration.

The issues

A. The Examiner rejected claims 9, 11, 14, and 15 under 35 U.S.C. § 102(b) as anticipated by Crawford[1] (Ans. 3-4).

B. The Examiner rejected claims 12 and 17 under 35 U.S.C. § 103(a) as obvious over Crawford, Caruso,[2] and Matheson[3] (Ans. 5-6).

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[1] Crawford et al., US 4,579,846, issued Apr. 1, 1986.
[2] Caruso, Frank S., WO 98/50044 A1, published Nov. 12, 1998.
[3] Matheson et al., Rofecoxib A Review of its Use in the Management of Osteoarthritis, Acute Pain and Rheumatoid Arthritis, 61 DRUGS 833-865 (2001).

A. 35 U.S.C. § 102(b) over Crawford

The Examiner finds that Crawford "teaches an anti-inflammatory composition for the treatment of gastric irritation that employs the anti-inflammatory piroxicam (a non-steroidal anti-inflammatory drug) with the antidepressant doxepin (a tricyclic anti-depressant[)]" (Ans. 3). The Examiner finds that Crawford "teaches that piroxicam and doxepin are co-administered in a single, combined formulation" (Ans. 3-4). The Examiner finds that Crawford teaches "a treatment composition comprising piroxicam and 20 mg doxepin with lactose and hydroxypropyl methylcellulose in a capsule" (Ans. 4).

Appellant contends that "Crawford's goal was an improved anti-inflammatory composition that reduced gastrointestinal (GI) irritation" (App. Br. 4). Appellant contends that "[l]arge amounts of ingredients are in his teachings as optionally in a composition - these are not within the scope of 'consisting essentially of' of the present invention, which does not include all these compounds, and whose goal is pain relief, not to reduce GI irritation" (App. Br. 4). Appellant contends that "not just that a preamble should be accounted patentable weight, but that those of skill in the art seeking a pain relief composition, would not be directed to Crawford who does not even mention pain" (App. Br. 4).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's finding that Crawford anticipates claim 9?

Findings of Fact

1. Crawford teaches "treatment with an antiinflammatory amount of piroxicam, treatment with a gastric antiirritation and ulcer inhibiting

amount of acetaminophen, doxepin, pirbuterol, diazepam, fanetizole, trimazosin, or a pharmaceutically-acceptable salt thereof (Crawford, col. 2, ll. 64-68).

2. Crawford teaches that the "piroxicam or its salt is dosed in a mammal, particularly man, in the range of 0.1 to 1 mg/kg/day. The second medicinal agent can be dosed separately, in which case the latter will be employed in an amount within (but generally lower in) the dosage range and according to dosage regimens" (Crawford, col. 3, ll. 46-51).

3. Crawford teaches that "[p]referably and conveniently, the piroxicam and a gastric irritation and ulcer inhibiting agent of the present invention are co-administered in a single, combined formulation" (Crawford, col. 3, ll. 55-58).

4. Crawford teaches that the

> the amount of piroxicam (or salt equivalent) for an average adult patient will generally be in the range of 5-50 mg/day in combination with:200 to 4000 mg/day of acetaminophen,
> 4 to 200 mg/day of doxepin;
> 3 to 100 mg/day of pirbuterol;
> 2 to 40 mg/day of diazepam; or
> 4 to 500 mg/day of trimazosin;
> an amount of the second medicinal agent generally sufficient to inhibit gastrointestinal irritation or ulcers which could otherwise be induced by the piroxicam in patients susceptible to this side effect.

(Crawford, col. 4, ll. 1-13).

5. Crawford teaches, in Example 7, "Capsules-Piroxicam (20 mg) and Doxepin (15 mg) The following ingredients are combined in the following proportions by weight:

piroxicam (milled)	20
doxepin hydrochloride	16 (equivalent to 15 of free base)
polyethylene glycol, average molecular weight, 4000	664

The mixture is thoroughly blended so as to obtain a uniform powder. The resultant mix (700 mg fill weight) is filled into hard gelatin capsules of a suitable size so as to obtain capsules of the desired potency" (Crawford, col. 8, ll. 14-29).

Principles of Law

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987).

Absent a clear indication in the Specification or claims of what the basic and novel characteristics of the claimed device actually are, the term "consisting essentially of" is construed as equivalent to "comprising." PPG Industries v. Guardian Industries Corp., 156 F.3d 1351, 1354 (Fed. Cir. 1998).

Analysis

Crawford teaches compositions which combine piroxicam, a non-steroidal anti-inflammatory drug with doxepin, a tricyclic antidepressant compound (FF 1-5). Crawford exemplifies a composition composed solely of 20 mg piroxicam, 15 mg doxepin, and polyethylene glycol, as a filler or diluent (FF 5).

Appellant contends that "Crawford's goal was an improved anti-inflammatory composition that reduced gastrointestinal (GI) irritation"

(App. Br. 4). Appellant contends that "[l]arge amounts of ingredients are in his teachings as optionally in a composition - these are not within the scope of 'consisting essentially of' of the present invention, which does not include all these compounds, and whose goal is pain relief, not to reduce GI irritation" (App. Br. 4).

We are not persuaded. Appellant provides no clear definition of the scope of "consisting essentially of" in the Specification, so even the inclusion of all of the elements disclosed in Crawford are reasonably interpreted as falling within the scope of the invention. PPG, 156 F.3d at 1354. Further, Example 7 of Crawford teaches a composition in a single pharmaceutically acceptable vehicle which contains only the diluent polyethylene glycol in addition to the two active ingredients (FF 5).

Appellant contends that "not just that a preamble should be accounted patentable weight, but that those of skill in the art seeking a pain relief composition, would not be directed to Crawford who does not even mention pain" (App. Br. 4).

We are not persuaded. In Catalina, the Federal Circuit explained that "preambles describing the use of an invention generally do not limit the claims because the patentability of apparatus or composition claims depends on the claimed structure, not on the use or purpose of that structure." Catalina Marketing International, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 809 (Fed. Cir. 2002). We therefore find that the preamble recitation of "chronic pain" does not limit the composition claims.

Conclusion of Law

The evidence of record supports the Examiner's finding that Crawford anticipates claim 9.

B. 35 U.S.C. § 103(a) over Crawford, Caruso, and Matheson

The Examiner finds that "Crawford does not teach the physiologically acceptable acid addition salt of the tricyclic antidepressant" (Ans. 5). The Examiner finds that Caruso "teaches that it is known to provide the anti-depressant doxepin as a pain-relieving agent in the hydrochloride salt form" (Ans. 5). The Examiner finds that "Matheson teaches that commonly used non-narcotic analgesics such as rofecoxib are used at doses up to 500 mg/day" (Ans. 5).

The Examiner finds it obvious "to provide the hydrochloride salt form with the expectation of achieving a composition suitable for pharmaceutical administration and to also provide doses of non-narcotic analgesics that fall in the range of 0.5 gm to 2.5 gm daily because these are doses that are commonly used for the treatment of different types of pain" (Ans. 6).

Appellant contends that "Caruso's contribution to an obviousness rejection is at most providing an 'antidepressant'" (App. Br. 6). Appellant contends that "Matheson and Figgitt is simply a review of Rafecoxib [sic Rofecoxib], a (COX)-2 inhibitor. It really stretches the imagination to postulate how those of skill would combine this publication with Crawford, and in doing so come up with the claimed invention" (App. Br. 7).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's finding that Crawford, Caruso, and Matheson render claims 12 and 17 obvious?

Findings of Fact

6. Caruso teaches "pain-alleviating antidepressants that can be used herein include . . . doxepin hydrochloride" (Caruso 4, ll. 7-10).

7. Matheson teaches that in "patients with postsurgical dental pain, rofecoxib 50 to 500mg was significantly better in providing total pain relief at 6 to 8 hours than either placebo ($p < 0.01$) or celecoxib 200mg ($p < 0.001$) (Matheson 848, col. 2).

8. Matheson teaches that at "doses ranging from 50 to 500mg, rofecoxib effectively relieved acute pain in 3 distinct settings: postoperative dental pain, primary dysmenorrhoea [sic dysmenorrhea] and 2 of 3 postoperative surgical pain subindications" (Matheson 861, col. 1).

9. The Specification teaches that "[s]tandard doses of such non-narcotic analgesics can be in the range of about 0.50 grams to about 2.6 grams daily for a typical adult. The standard dosage can vary depending on factors such as the size and age of the patient, as is known in the medical arts" (Spec. 3 ¶ 00010).

Principles of Law

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). "If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." Id. at 417.

Analysis

Claim 12

Crawford teaches compositions which combine piroxicam, a non-steroidal anti-inflammatory drug with doxepin, a tricyclic antidepressant compound (FF 1-5). Caruso teaches that doxepin may be used in the doxepin hydrochloride form (FF 6). Matheson teaches that rofecoxib may be used in amounts up to 0.5 g (FF 7-8).

Applying the KSR standard of obviousness to the findings of fact, we conclude that the person of ordinary creativity would have predictably followed the teachings of Caruso to use the hydrochloride form of doxepin with piroxicam in the combination treatment of Crawford. Such a combination is merely a "predictable use of prior art elements according to their established functions." KSR, 550 U.S. at 417.

Appellant contends that "Caruso's contribution to an obviousness rejection is at most providing an 'antidepressant'" (App. Br. 6).

We are not persuaded. Caruso teaches that the use of acid addition salts of doxepin were known for treatment (FF 6). We agree with the Examiner that an ordinary artisan would have predictably combined this known prior art element with Crawford.

Claim 17

Appellant contends that "Matheson and Figgitt is simply a review of Rafecoxib [sic Rofecoxib], a (COX)-2 inhibitor. It really stretches the imagination to postulate how those of skill would combine this publication with Crawford, and in doing so come up with the claimed invention" (App. Br. 7).

It is "well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable." In re Schreiber, 128 F.3d 1473, 1477 (Fed. Cir. 1997). Thus, the functional limitations directed to the intended dosages of "about 0.50 grams to about 2.6 grams daily" (FF9) do not serve to distinguish the claimed product from Crawford's prior art products which are inherently capable of being administered in these dosages. Even the pill of Crawford in Example 7 could be administered in dosages of 0.50 gm if sufficient numbers of the pills were consumed by the patient (FF 7). See id. at 1478-79 (holding that a prior art apparatus meeting all claimed structural limitations was anticipatory because it was inherently capable of performing the claimed function).

Moreover, while the evidence cited by the Examiner does not relate to piroxicam, the compound used by Crawford, the Specification teaches that "[s]tandard doses of such non-narcotic analgesics can be in the range of about 0.50 grams to about 2.6 grams daily for a typical adult. The standard dosage can vary depending on factors such as the size and age of the patient, as is known in the medical arts" (Spec. 3 ¶ 00010).

We are therefore persuaded that the ordinary artisan, selecting a dosage of a non-narcotic analgesic such as piroxicam, would reasonably have considered a dosage of 0.5 gram to 2.6 grams since these are acknowledged by Appellant's Specification to be standard doses. We are also unpersuaded that the compositions taught by the cited references would be incapable of administration at the dosage rate recited in claim 17.

Conclusion of Law

The evidence of record supports the Examiner's finding that Crawford, Caruso, and Matheson render claims 12 and 17 obvious.

CONCLUSION

In summary, we affirm the rejection of claim 9 under 35 U.S.C. § 102(b) as anticipated by Crawford. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejection of claims 11, 14, and 15, as these claims were not argued separately.

We affirm the rejection of claims 12 and 17 under 35 U.S.C. § 103(a) as obvious over Crawford, Caruso, and Matheson.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

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